UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAMES T. FAWCETT, on behalf of himself and all others similarly situated, Plaintiff, v. ALTANA PHARMA AG, ALTANA PHARMA US, INC., NYCOMED US INC, NYCOMED S.C.A. SICOR, WYETH, and WYETH PHARMACEUTICALS, INC, Defendants.	)	C.A. No. **JURY TRIAL DEMANDED**

COMPLAINT

James T. Fawcett ("Plaintiff"), on behalf of himself and all others similarly situated, for his Complaint against defendants Altana Pharma AG ("Altana"), Altana Pharma US, Inc., Nycomed S.C.A. SICOR ("Nycomed"), Nycomed US Inc., Wyeth, and Wyeth Pharmaceuticals Inc. (collectively "Defendants"), alleges as follows based on (a) personal knowledge, (b) the investigation of their counsel, including review of pleadings and court orders in patent infringement litigation pending in this District, and (c) information and belief.

I. NATURE OF THE ACTION

1. This is a class action brought under the federal and state antitrust laws and antitrust and/or deceptive statutes to remedy anticompetitive actions by Defendants to foreclose generic competition in the market for pantoprazole, a proton pump inhibitor sold by Defendants under the brand name Protonix. As alleged below, Defendants used various acts and practices as part of an overall scheme to improperly obtain and maintain an unlawful monopoly in the market for pantoprazole to the detriment of Plaintiff and the class of indirect purchasers of Protonix.

2. Protonix is used to treat gastrointestinal ("GI") disorders caused by stomach acid. Protonix blocks an enzyme in the wall of the stomach that produces the acid, decreasing production of stomach acid, and permitting damage to the GI tract to heal. At present, the pharmaceutical prescription market to treat GI disorders is valued at just over $20 billion a year, making it one of the largest and most profitable therapeutic areas in the pharmaceutical industry. Sales of Protonix are approximately $2.5 billion per year.

3. In order to participate in this lucrative market and to prevent erosion of its market share, Defendants engaged in a course of anticompetitive conduct intended to secure an unlawful monopoly through procurement of an unenforceable patent, and to extend their unlawful monopoly by preventing entry of inexpensive generic substitutes.

4. First, in connection with procuring the patent for pantoprazole from the United States Patent and Trademark Office ("PTO"), Defendants (or the patent applicants working on their behalf) knowingly and intentionally made false representations and deliberate omissions of material facts concerning patentability with the intent to deceive the patent examiner. These omissions and misrepresentations concerned critical differences between the claimed compounds and the prior art compounds with respect to half-life, stability, test methods, comparative testing, and animal studies. The patent examiner justifiably relied on these false representations and omissions in granting the patent. Had the patent examiner been given the opportunity to evaluate the differences in test methods and results, the patent would not have issued or would not have issued as claimed.

5. Second, after two generic pharmaceutical manufacturers, Teva Pharmaceuticals, Inc. ("Teva") and Sun Pharmaceuticals Industries, Ltd. ("Sun"), filed applications for approval to sell generic versions of Protonix, Defendants commenced baseless patent infringement actions

against them. In a decision dated September 6, 2007, on Defendants' motion for preliminary injunction, the Court ruled that Defendants' infringement claims would be unsustainable because pantoprazole was an obvious variation of known compounds. *Altana Pharma AG and Wyeth v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 04-2355 (JLL) (Sept. 6, 2007). Defendants' actions against Teva and Sun were objectively baseless. Defendants knew or should have known that the patent upon which their infringement litigation rested was invalid as obvious, and unenforceable, and commenced the litigation for the purpose of preventing the generic manufacturers from marketing a lower-priced generic product.

6. As a result of Defendants' anticompetitive conduct, Protonix purchasers have been denied the benefits of free and unrestrained competition in the pantoprazole market. More specifically, Plaintiff and the Class have been denied the opportunity to choose between brand-name Protonix and lower-priced generic versions and are being made to pay supracompetitive prices for pantoprazole.

7. In Count I, Plaintiffs seek a judgment pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of Defendants' unlawful monopolistic practices in violation of §2 of the Sherman Act, 15 U.S.C. §2. Neither Plaintiffs nor the Class seek any relief under §4 of the Clayton Act, 15 U.S.C. § 15.

8. In Count II, Plaintiffs and the Class seek damages, penalties, and injunctive relief for Defendants' violations of the state antitrust and/or unfair and deceptive practices statutes.

9. In Count III, Plaintiffs and the Class seek equitable remedies based on Defendants' unjust enrichment.

II. JURISDICTION AND VENUE

10. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331, 1332(d)(2), and 1337(a), and 15 U.S.C. §§ 22 and 26. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. §1367(a).

11. Venue is proper within this District under 15 U.S.C. §22 and 28 U.S.C. §1391(b) because Defendants are found or transact business within this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District.

III. THE PARTIES

12. Plaintiff James T. Fawcett is an individual residing at 1029 Spaight Street, Madison, WI 33154. During the relevant period, plaintiff was prescribed and paid co-pays for Protonix. Had a generic version of Protonix been available, plaintiff would have substituted the generic for Protonix and would have paid co-pays for the generic version of Protonix that were lower than those he paid for Protonix.

13. Defendant Altana Pharma AG ("Altana") is a corporation incorporated and existing under the laws of Germany, having its principal place of business in Germany.

14. Defendant Altana Pharma US, Inc., a United States subsidiary Altana, has its principal place of business in Florham Park, Morris County, NJ.

15. Defendant Nycomed S.C.A. SICOR ("Nycomed") is a holding company located in Luxembourg. On December 29, 2006, Nycomed acquired Altana.

16. Defendant Nycomed US Inc., f/k/a Altana Inc., a United States subsidiary of Nycomed, has its principal place of business in Melville, NY.

17. Wyeth is a corporation incorporated under the laws of Delaware with its headquarters located in Madison, Morris County, NJ.

18. Wyeth Pharmaceuticals Inc., a subsidiary of Wyeth, has its principal place of business in Collegeville, PA, is the holder of New Drug Application ("NDA") No. 20-987, by which the FDA first granted approval of Protonix.

19. Altana is the owner of United States Patent No. 4,758,579 (the "'579 patent"), which issued on February 9, 1988. Wyeth is the exclusive licensee of the '579 patent in the United States.

IV. INTERSTATE TRADE AND COMMERCE

20. Defendants' efforts to monopolize and restrain competition in the market for Protonix have substantially affected interstate and foreign commerce. During all or part of the Class Period, Defendants manufactured and sold substantial amounts of Protonix in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. During all or part of the Class Period, Defendants transmitted funds as well as contracts, invoices and other forms of business communications, and employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. These activities were within the flow of and have substantially affected interstate commerce.

V. RELEVANT MARKET

21. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is all pantoprazole products – i.e., Protonix (in all its forms and dosage strengths) and its AB-rated generic equivalents. Sellers that desire to manufacture, market, or sell Protonix tablets in the United States must receive FDA approval. The only drug products that are freely substitutable by a pharmacist with brand-name Protonix tablets are those drugs that receive an AB-rating from the FDA. By foreclosing entry of AB-rated equivalents of Protonix into the

market, Defendants have been able to profitably maintain the price of their branded pantoprazole products well above competitive levels and control 100% of the relevant market.

22. The relevant geographic market is the United States as a whole (for Counts I and III) and the Indirect Purchaser States (for Count II).

23. Defendants' market share in the relevant market at all times was 100%.

VI. MARKET EFFECTS

24. The acts and practices of Defendants had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Protonix from generic competition in the relevant market. Defendants' actions have allowed, and continue to allow, Defendants to exclude competition in the relevant market, to the detriment of all pantoprazole purchasers.

25. Defendants are the only suppliers of products in the pantoprazole market that are free of any threat of patent infringement challenges and, at present, Defendants' pantoprazole products are the only pantoprazole products commercially available in the United States.

26. Through their anticompetitive conduct, Defendants have been able to charge supracompetitive prices for pantoprazole.

27. The generic manufacturers of pantoprazole invested a significant amount of time, effort, and resources in developing generic pantoprazole, and preparing and filing their ANDAs to enter the Protonix market upon final FDA approval of their ANDAs. When the generic manufactures filed their ANDAs, they intended to and were ready, willing and able to enter the Protonix market upon final FDA approval of their ANDAs. But for Defendants' misconduct, this would have occurred on April 19, 2006.

28. If manufacturers of generic pantoprazole been able to enter the market and to compete effectively with Defendants, Plaintiff would have substituted lower-priced generic

pantoprazole for the higher-priced brand-name Protonix for some or all of its pantoprazole requirements, and would have paid lower prices for its remaining Protonix purchases.

VII. DAMAGES TO PLAINTIFFS AND MEMBERS OF THE CLASS

29. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Protonix. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for its pantoprazole requirements. By preventing generic competitors from entering the market, Defendants injured Plaintiff and members of the Class in their business or property by causing them to pay more for Protonix than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws are intended to preserve.

VIII. FACTUAL ALLEGATIONS

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand-Name Drugs

30. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 ("FDCA"), a manufacturer of a new drug must obtain approval of the Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

31. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman amendments, called the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman"). The purpose of Hatch-Waxman was to hasten the delivery of inexpensive generic drugs to the market while respecting the patent rights of brand-name drug patent holders.

32. Typically, generic versions of brand-name drugs are priced significantly below their brand-name counterparts. Because of these price differences and other institutional features of the pharmaceutical market, generic versions are commonly substituted for their brand-name counterparts. In fact, in every state, pharmacists are permitted (and in some states, required) to substitute the generic product for a brand-name product unless the doctor has stated that the prescription for the brand-name product must be dispensed as written.

33. As additional generic manufacturers enter the market, prices for generic versions of a drug decrease predictably because of competition among generic manufacturers, and the loss of sales volume by the brand-name drug to the corresponding generic accelerates. Generic competition enables purchasers to (a) purchase generic versions of the brand-name drug at a substantially lower price and (b) purchase the brand-name drug at a reduced price.

34. Until a generic manufacturer enters the market, there is no AB-rated bioequivalent generic drug that competes with the brand-name drug, and therefore the brand-name manufacturer can continue to charge supracompetitive prices profitably without material loss to sales volume. Consequently, brand-name drug manufacturers have a strong interest in seeking to delay the introduction of generic competition into the market.

35. Hatch-Waxman represents a significant effort by Congress to hasten the delivery of generic drugs to the market. The principal mechanism used by Congress was to eliminate the need for generic manufacturers to file a lengthy and costly NDA to obtain FDA approval for generic versions of brand-name pharmaceuticals. Instead, under Hatch-Waxman, to obtain approval, the generic manufacturer is permitted to file an Abbreviated New Drug Application ("ANDA") that incorporates the scientific findings of safety and effectiveness included in the brand-name drug manufacturer's original NDA and then shows only that the proposed generic

drug is "bioequivalent" to the brand-name drug, *i.e.*, that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug.

36. Once bioequivalence is demonstrated, the FDA assigns an "AB" rating to the generic drug, permitting it not only to be sold, but also to be substituted (and in some instances, *required* to be substituted) for the brand-name drug at the pharmacy dispensing the drug.

37. To protect brand-name manufacturers' ability to enforce their patents against infringement through this abbreviated approval process, Hatch-Waxman also streamlined the patent enforcement process, providing that under certain conditions, the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand-name drug for up to 30 months if the patent holder initiated a patent infringement lawsuit against the generic manufacturer.

38. When the FDA approves a brand-name manufacturer's NDA, the FDA publishes the patents that claim the approved drug or method of use in a publication known as the "Orange Book." In listing patents in the Orange Book, the FDA relies completely on the brand-name manufacturer for information concerning the validity of the patents. The FDA does not check the representations supplied by the brand-name manufacturer independently for accuracy or trustworthiness.

39. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand-name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand-name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

40. If a generic manufacturer files Paragraph I or II certifications, the FDA must act on the application within 180 days of receipt. If a generic manufacturer files a Paragraph III certification, the FDA can proceed with the ANDA approval process. However, "final approval" cannot be granted until expiration of the applicable patents.

41. If a generic manufacturer files a Paragraph IV certification, however, a brand-name manufacturer may delay the final FDA approval of the ANDA by suing for patent infringement. Specifically, if the brand-name manufacturer initiates a patent infringement action against the generic filer within 45 days of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of either (a) the passage of 30 months or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. During the pendency of the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would qualify for final approval but for the 30-month stay, but cannot authorize the generic manufacturer to go to market. Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand-name drug manufacturer may delay the date of final approval of the generic drug, and the generic drug's entry into the market.

42. One result of the Hatch-Waxman statutory and regulatory provisions is that brand-name manufacturers have a strong incentive to obtain, list, and enforce patents against prospective generic entrants even if the patent is held ultimately to be invalid or not infringed by the generic rival's application. As a practical matter, the brand name manufacturer can gain a effective litigation victory just be filing the lawsuit, since such filing confers an extension of the brand product manufacturer's monopoly for up to two and a half years. In consequence, Hatch-Waxman relies on the brand-name manufacturer to refrain from (a) listing patents that were improperly procured or invalid or (b) bringing suit without proof that the generic applicant actually infringes a valid and enforceable patent held by the brand-name manufacturer.

43. Abuse by brand-name manufacturers of the Hatch-Waxman patent protections through improper patent listing or commencement of baseless litigation improperly prevents generic competitors from bringing their less expensive AB-rated substitute products to market. Such conduct is anticompetitive, harms purchasers of pharmaceutical products, and violates the laws of antitrust.

B. Protonix and Generic Competition

44. Protonix is a prescription drug used to treat GI disorders caused by stomach acid. It is in a class of drugs called proton pump inhibitors also known as a substituted benzimidizole. Like other proton-pump inhibitors, Protonix blocks the enzyme in the wall of the stomach that produces acid. By blocking the enzyme, the production of acid is decreased, permitting healing of the GI tract to occur.

45. Protonix is sold in 20 mg and 40 mg extended release tablets, and in an IV form. The generic name for the active ingredient in Protonix is pantoprazole sodium.

46. Protonix is manufactured and marketed by Defendants Altana, Nycomed and Wyeth. Altana is currently owner of the '579 patent, which claims pantoprazole. Nycomed is

the parent corporation of Altana. Wyeth Pharmaceuticals, Inc., a wholly-owned subsidiary of Wyeth, holds an improved NDA for pantoprazole sodium, i.e., Protonix.

47. Defendants' sales of Protonix in the United States in 2006 were approximately $2.5 billion, making it one of the highest grossing pharmaceutical products in the country.

48. In April 2004, Teva filed ANDA No. 77-056 seeking approval to market 20 mg and 40 mg extended release pantoprazole sodium tablets in the United States. Teva is among the largest generic pharmaceutical product manufacturers in the world. In January 2005, Sun filed ANDA No. 77-058 seeking approval to market generic pantoprazole tablets.

49. Prior to these filings, no potential generic competitor had filed an ANDA seeking to market a generic version of Protonix or challenge Defendants' monopoly position in the lucrative Protonix market.

50. Within the time required under Hatch-Waxman, Defendants filed patent infringement actions against Teva and Sun, triggering Hatch-Waxman's automatic 30-month stay provision.

51. On or about April 19, 2006, the FDA granted Teva's ANDA tentative approval. On or about June 22, 2006, the FDA granted Sun's ANDA tentative approval.

52. Because of the 30-month automatic stay, the FDA could not grant final approval to these ANDAs, neither Teva nor Sun could bring their generic versions of Protonix to market, and the generic versions were unavailable to purchasers in the pantoprazole market.

53. The FDA granted final approval to Teva to market generic versions of Protonix on August 2, 2007, the day the Hatch-Waxman stay expired. The FDA granted final approval to Sun to market its generic Protonix on September 7, 2007.

C. Defendants' Fraudulent Procurement of the '579 Patent

54. Altana procured the '579 patent from the PTO by fraud. Altana engaged in a pervasive pattern of misconduct involving deliberate misrepresentations of, and failures to disclose, highly material cats to the PTO. Absent the fraud, the '579 Patent would not have issued.

55. Applicants for United States patents have a duty of candor with respect to the PTO requiring the accurate disclosure of material information. Material information is information that a reasonable examiner would consider important in deciding whether to allow the application to issue as a patent. Applicants may not disregard their duty either by intentionally misrepresenting material facts or by intentionally withholding them from the PTO. Such conduct constitutes inequitable conduct and may render a patent unenforceable. Where, as here, the patent would not have issued absent intentional misrepresentations and omissions, the conduct also creates antitrust liability.

56. In 1984, Altana claimed that its scientist Dr. Bernhard Kohl invented pantoprazole based on a new substituted benzimidazole compound. Altana later applied for the '579 patent on this claimed invention. The application, however, was supported by intentional and material misrepresentations and omissions intended to deceive the PTO.

57. Prior to the claimed invention of pantoprazole, there were many substituted benzimidazoles in the prior art whose chemical structure was similar to the chemical structure of pantoprazole. One such compound was omeprazole, the active pharmaceutical ingredient in the first publically available proton pump inhibitor, sold under the brand name Prilosec. In addition, compound 12 of Altana's own U.S. Patent No. 4,555,518 (the "'518 patent"), another prior art patent, is virtually identical to pantoprazole, differing only in the substitution of one group on the molecule, the methyl group, at the position of the pyridine ring.

58. As a result of the chemical structural similarities of pantoprazole to the prior art compounds, including omeprazole and compound 12, the PTO initially rejected the '579 patent. Specifically, the examiner concluded that the only difference between the claimed compounds and the prior art compounds was in the substitution of the pyridine ring of the molecule – that in either the 3-position or the 5-position of the pyridine ring an alkyl group was changed to an alkoxy group – and that this difference was insufficient to support patentability of the pantoprazole application.

59. To avoid prior art preclusion, the patent applicants subsequently argued that they had discovered that pantoprazole was "substantially" more chemically stable in solution in comparison to prior art compounds, suggesting that the alleged increased stability would lead to decreased side effects of the drug. The patent applicants then submitted data to the PTO through Dr. Uwe Kruger, Head of the Department of Physical Organic Chemistry at Altana, in support of their argument of increased stability. The PTO was ultimately persuaded by the claims of pantoprazole's increased stability over the prior art, and granted the '579 patent.

60. In connection with their prosecution of the '579 patent, the patent applicants, Dr. Kruger, and others involved in the prosecution of the '579 patent, withheld stability data from the PTO indicating that the stability of pantoprazole and omeprazole, as well as other prior art compounds, was similar. In fact, not only did the withheld data indicate that the stabilities of the compounds were much more similar than the data submitted to the PTO had indicated, but, as Altana itself recognized, the withheld data was obtained under more reliable and realistic testing conditions than the data submitted to the PTO.

61. The patent applicants also withheld information about the reliability of the potency data they had submitted during the prosecution upon the express request of the patent

examiner. During the prosecution of the '579 patent application, Altana had foreign patent applications pending for proton pump inhibitors, which included potency testing data from Shay-rat studies. A competitor cited literature against Altana in the prosecution of these foreign applications that indicated that the Shay-rat testing method was unreliable because it produced "false positives." After the Shay-rat data was challenged, Altana abandoned the foreign patent applications. The applicants for the '579 patent failed to disclose the literature questioning the reliability of the Shay-rat method or Altana's competitor's claims about the unreliability of such data.

62. At the time that the application for the '579 patent was prepared and during its prosecution in the PTO, Altana believed that the invention claimed in the application for the '579 patent would be a commercially successful product and could make Altana a major participant in the lucrative market for pharmaceutical prescription that treat GI disorders.

63. With the long-sought allowance of the application within their reach, Altana feared providing to the PTO any information that could have raised questions in the mind of the patent examiner, jeopardize an allowance of the claims, or delay the issuance of the patent.

64. Accordingly, Altana made these and other deliberate misrepresentations and omissions of fact material to patentability in order to deceive the patent examiner. The examiner justifiably relied on these misrepresentations and omissions in granting the patent. But for these misrepresentations or deliberate omissions, the patent would not have been granted.

1. Misrepresentations and Omissions Concerning the Half-Life of Pantoprozole Compared to the Half-Lives of Compounds in the Prior Art

65. During the prosecution of the application for the '579 patent, Altana submitted declarations under 37 C.F.R. 1.132 to the PTO containing data comparing the stability of certain chemical compounds contained in the application for the '579 patent to compounds in the prior

art. These declarations were submitted in response to a prior rejection of the application for the '579 patent based on prior art.

66. The applicants for the '579 patent argued to the PTO that the most important factor supporting approval of the '579 patent application was the alleged significant difference in half-lives of the tested compounds covered by the then-pending claims of the '579 patent application and the half-lives of the tested prior art compounds. The patent applicants argued that the purported greater stability of the claimed compounds over the prior art would result in a reduction of side effects.

67. The declarations, submitted by Dr. Uwe Kruger, reported the half-lives of the compounds in a buffer/acetonitrile solution at pH 5. In this solution, the declarations asserted that the half-lives of the test compounds covered by the '579 patent application had significantly longer half-lives than the half-lives of the tested prior art compounds. Specifically, the patent applicants told the PTO that the half-life of pantoprazole was at least 21 hours and may extend beyond 40 hours, while the half-life of omeprazole was only 5 hours. Omeprazole, sold commercially as Prilosec, was identified by Altana as "the gold standard" of proton pump inhibitors, *i.e.*, the molecule against which other potential proton pump inhibitor molecules should be evaluated.

68. Altana further represented that the improved chemical stability of the claimed compounds over the prior art constituted "unexpected results."

69. Altana, however, switched the test solution from buffer/acetonitrile to buffer/methanol, claiming the buffer/acetonitrile solution was less reliable than the buffer/methanol solution, and that the buffer/methanol solution reflected relevant conditions better than the buffer/acetonitrile solution. The buffer/methanol solution yielded data showing

that the half-life of pantoprazole was only 2.9 hours and the half-life of omeprazole was only one hour. Because Altana claimed that the buffer/methanol solution stability data was more representative of pantoprazole's stability in humans, Altana provided this data to the FDA for approval to market pantoprazole.

70. Altana, the patent applicants, and declarant Dr. Kruger, however, failed to disclose to the PTO that they had made this switch. The withheld data shows that the half-lives of pantoprazole and the prior art compounds were much closer than shown by the data that was initially submitted.

71. This deliberately omitted data and information were material to the patentability of the claims. The patent examiner relied upon the differences in the stability of the compounds provided by Altana in her decision to allow the '579 patent application to issue.

72. The only reasonable inference that can be drawn from the decision to withhold the data was that the patent applicants, Dr. Kruger, and others involved with the patent prosecution believed that the data was detrimental to their argument for patentability, and they therefore withheld the data with intent to deceive the PTO.

2. Misrepresentations and Omissions Concerning Comparative Tests

73. When Altana submitted its NDA seeking permission to market a pantoprazole-containing product, it submitted other information to the FDA regarding the half-life of pantoprazole that was contrary to the position taken by the applicants for the '579 patent during the prosecution before the PTO.

74. In the January 1987 and April 1987 Kruger Declarations, Dr. Kruger stated that the stability tests reported therein were "comparative tests." These statements were meant to give the patent examiner the impression that the reported tests were done at the same time using identical testing conditions and procedures and in response to the patent examiner's requests in

pending Office Actions for data supporting patentability. Defendants never informed the patent examiner that these tests were not side-by-side comparison tests. Differences in experimental conditions, such as, for example, Altana's use of different equipment at different times, could have caused significant differences in test results. As such, the non-disclosure was knowing and the information material.

3. Misrepresentations and Omissions Concerning Temperature of Tests

75. The '579 patent applicants argued or implied to the PTO that the stability experiments were indicative of the stability of the compounds tested in the human body, in human cells, in mammals, and in mammal cells. The acetonitrile solvent system stability experiments, however, were conducted at room temperature. The patent applicants failed to inform the PTO that the experiments were performed at room temperature rather than at the temperature of the human body, human cells, mammals, and mammal cells. The fact that the acetonitrile solvent system stability experiments reported to the PTO were performed at room temperature rather than at the higher temperature of the human body, human cells, mammals and mammal cells indicated that the half-lives of the tested compounds were significantly longer than the half-lives of the tested prior art compounds. This fact was material to the patentability of the claims, and the failure to disclose this information to the PTO was knowingly committed with intent to deceive the PTO.

4. Misrepresentations and Omissions Concerning Premature Degradation

76. In the January 1987 and April 1987 Kruger Declarations and in arguments presented to the patent examiner, the patent applicants represented that the prior art and claimed compounds were subject to premature degradation outside the parietal cell in the lysosomes where the pH was reported to be "in the range of 5," that is, a chemical reaction would occur before the compounds reached the parietal cells in the mucosal lining, the intended site of action.

The patent applicants also represented that such premature degradation could cause unwanted and unspecified side effects.

77. Neither the Kruger Declarations nor any of the arguments presented to the patent examiner revealed that at the time these statements were made, there was insufficient scientifically acceptable evidence to support the theory concerning premature degradation and its consequence.

78. Since this theory was the basis for using the conditions in the stability testing reported to the PTO in the Kruger Declarations, the applicants' failure to inform the PTO that the stability testing was based on an unproved theory was material to the patentability of the '579 patent and was done intentionally and with an intent to deceive the PTO.

5. Misrepresentations and Omissions Concerning the Suitability of Shay Rats for Studies

79. To support patentability of the pending claims over the cited prior art and to induce the PTO to allow these claims to issue, the applicants presented data from experiments involving the administration of certain compounds to Shay rats. During the prosecution of the '579 patent, Altana was aware that questions had been raised in the applicable scientific and technical literature concerning the appropriateness of using Shay rats to model human activity.

80. In the prosecution of European and Australian applications directed to the same class of compounds as the compounds claimed in the '579 patent, Astra, the maker of omeprazole, supplied numerous scientific studies challenging the Shay-rat studies as being unreliable as resulting in excessive false positives, and incapable of modeling human activity. The studies further showed that dogs provide a more specific model with good correlation to activity in man. Altana abandoned the European application via letter dated June 19, 1996. Altana also abandoned the Australian application after Astra's challenges.

81. During the prosecution of the '579 patent, the applicants were aware that experiments using animals other that the Shay rats with certain compounds covered by the then-pending claims of the '579 patent and certain prior art compounds produced different relative results among the tested compounds than when using Shay rats. Nevertheless, the applicants submitted the Shay-rat potency data to the PTO without disclosing Astra's arguments regarding the unreliability of the Shay-rat potency studies, or the supporting literature.

82. The applicants for the '579 patent, their agents, and others involved in the prosecution of the '579 patent knew the reliability of the potency data, or lack thereof, to be material to the examination of the application for the '579 patent, as the PTO has specifically cited the lack of potency data as part of its ground for rejecting the claims during the prosecution of the '579 patent.

83. All of these facts regarding the Shay-rat experiments were material to the patentability of the '579 patent, and the failure to disclose this information to the PTO was knowing and intended to mislead the PTO.

6. Misrepresentations and Omissions Concerning the Comparative Nature of the Shay-Rat Studies

84. In a declaration submitted by Dr. Konrad Heintze dated December 1987, Dr. Heintze stated that the Shay-rat tests reported therein were "comparative tests." This statement was meant to give the patent examiner the impression that the reported tests were all done at approximately the same time and in response to the patent examiner's requests in pending Office Action for data supporting patentability. The applicants never informed the patent examiner that these tests were not side-by-side comparison tests.

D. Defendants' Baseless Prosecution of Infringement Claims

85. Under 35 U.S.C. §103(a), the PTO cannot grant a patent on an invention if the "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains."

86. An invention is obvious if a person of ordinary skill in the art views the differences between the claimed invention and the prior art as a predictable variation, and the art taught the benefit of making the variation. In chemical cases, a compound is *prima facie* obvious if the art provides the reason for a chemist to modify a known compound in a particular manner to create the claimed compound.

87. Knowing that the '579 patent was invalid as obvious and unenforceable, Defendants engaged in baseless enforcement litigation for the improper purpose of impairing the generic manufacturers' ability to enter the market with a lower-priced generic version of pantoprazole. As a result of Defendants' anticompetitive conduct, Plaintiff and the Class of indirect purchasers paid more than they would have for products containing pantoprazole than had Defendants not filed the patent infringement litigation.

1. The '579 Patent is Invalid as Obvious over the Prior Art

88. Prior art compounds share structural similarities with the compounds claimed in the '579 patent. Prior art references, when combined, further provided motivation and reason for one of ordinary skill in the art to modify known compounds in a particular manner to make the compounds claimed in the '579 patent.

89. The pantoprazole molecule contains a "substituted benzimidazole" structure as its "chemical backbone."

90. The chemical backbone consists of three basic parts: (1) a benzimidazole group, (2) connected to a pyridine ring, (3) through a methylsufinyl bridging group.

91. Various drug companies used this chemical backbone as a starting point for developing the class of proton pump inhibitors by substituting different chemical groups on the benzimidazole group and pyridine ring. This backbone is common to the four other proton pump inhibitors that are FDA approved — omeprazole (Prilosec), lansoprazole (Prevacid), rabeprazole (Aciphex), and esomeprazole (Nexium).

92. Altana patented a class of 18 compounds with fluorine substitutions on the benzimidazole ring. The patent issued as the '518 patent.

93. The '518 patent discloses "Compound 12," a substituted benzimidazole backbone having a methyl group ($-CH_3$) at ring position 3, and one methoxy group ($-OCH_3$) at ring position 4 on the pyridine ring. Compound 12 was one of the more potent compounds and a natural choice for further investigation and development.

94. Altana filed a patent application for pantoprazole with the PTO on June 14, 1985. The patent examiner initially rejected the application as obvious over two other Altana patents, the '518 patent, and a patent claiming another compound, omeprazole, also containing a substituted benzimidazole structure. The patent examiner also rejected the application as unpatentable under the doctrine of obviousness type double-patenting in view of a third patent. The patent examiner repeated these rejections several more times during the patent prosecution.

95. After Altana submitted data indicating that the compounds in the '579 patent were comparable in potency to the prior art compounds, yet exhibited superior pH 5 stability to those compounds, the patent examiner withdrew her rejections. The '579 patent issued February 9, 1988.

96. A 1984 journal article by Dr. Sachs ("Sachs article") and a 1960 article by Dr. A. Bryson ("Bryson article") both provided motivation for modifying Compound 12 of the '518 patent to create pantoprazole.

97. The Sachs article taught one of ordinary skill in the art that to design an effective proton pump inhibitor, the compound should have a pKa of 4, *i.e.*, be chemically stable enough to survive in the slightly acidic regions (pH 5) of the body, yet not so stable as to be unreactive in the highly acidic parietal cells (pH 1), where the compound needs to inhibit acid production. The Sachs article further teaches that a compound of pKa 4 would achieve this result, and that the way to lower the pKa of the compound was to lower the pKa of the pyridine nitrogen.

98. Dr. Sachs testified at his deposition in *Altana Pharma AG and Wyeth v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 04-2355 (JLL) that his 1984 article implied that an effective drug should be stable at pH 5; that the pKa is relevant to both selectivity and stability of the drug; and that the key to accumulation of drug in the parietal cells is the pKa of the pyridine ring, not the pKa of the benzimidazole group.

99. Thus, the Sachs article provided the motivation to modify Compound 12 to create pantoprazole by lowering the pKa of the pyridine ring to a pKa of 4.

100. Additionally, the patent for omeprazole, U.S. Patent No. 4,255,431 (the "'431 patent"), teaches that several compounds, including methoxy groups, can be substituted at the 3 position of the pyridine ring.

101. The Bryson article teaches the pKa values of various chemical groups, including methoxy groups at the 3 position of the pyridine ring. According the Bryson article, a methoxy group at position 3 has a pKa value of 4, but a methyl group at the same position has a pKa of 5. This information, coupled with the teachings of the Sachs article, suggests the creation of a

proton pump inhibitor molecule superior to Compound 12 by substituting a methoxy group for the methyl group at position 3 in the pyridine ring, which would result in a compound with a pKa of 4.

102. Thus, when the teachings of the Sachs article and the '431 patent are combined with the teachings of the Bryson article and the structure of Compound 12, one of ordinary skill in the art would have been motivated to modify the structure of Compound 12 to include a methoxy group at position 3 of the pyridine ring to create a compound with better pH 5 stability. Such a predictable variation of the compound, and the understanding of the benefit of making such a modification, renders pantoprazole a predictable variation of Compound 12, and the '579 patent invalid as obvious.

103. Furthermore, the timeline describing the discovery of pantoprazole is sufficiently persuasive as to the obviousness of pantoprazole. Compound 12 was first synthesized on March 22, 1984, the same day that the Sachs article published. Dr. Kohl claimed that he developed the synthetic scheme for pantoprazole in May 1984. In its June 16, 1984 Swiss patent application, Altana claimed that pantoprazole had superior pH 5 stability, reduced side effects, and a wider therapeutic range over other substituted benzimidazole. However, the pantoprazole molecule was not synthesized until April 25, 1985, eleven months later. Thus, the applicant knew that pantoprazole would have superior pH 5 stability over Compound 12 and other prior art compounds because of the teachings of Sachs and Bryson *before* they ever synthesized the compound.

104. At all times, pantoprazole has been a predictable variation of the prior art, with the prior art providing ample reason for Altana chemists to modify a known compound in a particular manner to create pantoprazole, rendering the '579 patent invalid.

2. In their Action to Enforce the Invalid '579 Patent, Defendants Engaged in Sham Litigation

105. Teva filed its ANDA No. 77-056 on or about April 6, 2004, for approval to market a pantoprazole sodium delayed-release tablet in the United States.

106. Teva sent notice letters related to ANDA No.77-056 pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to Altana and Wyeth, which notice letters were received by Altana on or about April 8, 2004, and by Wyeth on or about April 7, 2004, respectively.

107. On or about May 20, 2004, Altana and Wyeth filed a complaint for patent infringement that alleged that Teva's proposed product infringed the '579 patent.

108. On or about April 19, 2006, the FDA gave tentative approval to Teva's ANDA.

109. On or about August 2, 2007, the FDA gave final approval to Teva's ANDA.

110. Other generic manufacturers later filed other ANDAs for approval to market a pantoprazole sodium delayed-release tablet in the United States.

111. Sun Pharmaceuticals sent notice letters related to ANDA No.77-058 for generic pantoprazole tablets, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to Altana and Wyeth, which notice letters were received by Altana and Wyeth on or about March 1 and 5, 2005, respectively.

112. On or about April 13, 2005, Altana and Wyeth filed a complaint for patent infringement that alleged that Sun's proposed product infringed the '579 patent.

113. On or about June 22, 2006, the FDA gave tentative approval to Sun's ANDA.

114. On or about September 7, 2007, the FDA gave final approval to Sun's ANDA.

115. Before Defendants commenced litigation against the generic manufacturers, they knew of the inequitable conduct that occurred in procuring the '579 patent and that the '579 patent was unenforceable.

116. Before Defendants commenced litigation against the generic manufacturers, they also knew that the '579 patent was invalid as obvious over the prior art.

117. Although Defendants knew that the '579 patent was unenforceable and invalid, they nevertheless commenced litigation to enforce the '579 patent. Defendants' purpose in commencing and maintaining these baseless actions was to interfere improperly with the generic manufacturers' ability to enter the pantoprazole market, thereby further perpetuating their monopoly power.

118. In particular, Defendants knew that the filing of actions against Teva and Sun would trigger the automatic 30-month stays of FDA final approval of the generic versions of pantoprazole under Hatch-Waxman, thereby further extending their monopoly.

119. As a direct result of Defendants' knowing and willful commencement of sham litigation to enforce the invalid and unenforceable '579 patent against competitors, Defendants have extended their monopoly power over pantoprazole market, resulting in overcharges to Plaintiff and the Class of indirect purchasers. But for Defendants' baseless actions, Teva would have been able to launch its generic versions of pantoprazole as early as April 19, 2006.

IX. CLASS ACTION ALLEGATIONS

120. Plaintiff brings this action on behalf of itself and as representative of a class defined pursuant to Rule 23 of the Federal Rules of Civil Procedure, sub-sections 23(a) and 23(b)(2) and/or (b)(3) as follows:

> All persons or entities in the United States of America and Puerto Rico, who from April 19, 2006, to the present (the "Class Period") indirectly purchased, paid for and/or reimbursed for Protonix and any generic version thereof for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class").
>
> Excluded from the Class are Defendants, its subsidiaries and affiliates; all government entities (except for government-funded

> employee benefit plans); all persons or entities that purchased Protonix for purposes of resale, or directly from Defendants or its affiliates; and the judge in this case and any members of his/her immediate family.
>
> This class shall be certified as to Plaintiff's claims for violations of the state antitrust and consumer protection laws in the following states: Arizona, California, District of Columbia, Florida, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, including all elements of liability and all defenses to such claims.
>
> This class shall also be certified as to Plaintiff's claims for injunctive relief and violations of the common law of unjust enrichment in every state and the District of Columbia, including all elements of liability and all defenses to such claims.

121. Plaintiff, on behalf of itself and all other indirect purchasers who are members of the Class, seek injunctive, monetary, and injunctive relief against Defendants based on allegations of monopolization of, and an attempt to monopolize, the market for Protonix.

122. Plaintiff seeks class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory, injunctive and equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.

123. Declaratory and injunctive relief is appropriate under Rule 23(b)(2) because, as alleged herein, Defendants have acted on grounds generally applicable to the Class, thereby making appropriate declaratory and final injunctive relief with respect to the Class as a whole.

124. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that the Class numbers in the tens or hundreds of thousands.

125. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants, *i.e.*, they paid artificially inflated prices for pantoprazole and were deprived of the benefits of

competition from cheaper generic versions of Protonix as a result of Defendants' wrongful conduct.

126. Plaintiff will fairly and adequately protect and represent the interests of the Class. Defendants' interests are coincident with, and not antagonistic to, those of the Class.

127. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

128. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

129. Questions of law and fact common to the Class include:

a. whether the '579 Patent was procured by fraud on the PTO and is therefore unenforceable and invalid;

b. whether the Defendants litigation asserting infringement of the '579 Patent as described herein was baseless and initiated for an improper purpose;

c. whether Defendants unlawfully delayed or prevented generic manufacturers Teva and Sun from coming to market in the United States;

d. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

e. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

f. whether Defendants maintained monopoly power in the relevant market by delaying generic entry;

g. whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and

h. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class, and if so, the appropriate measure of damages.

130. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

131. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

X. CLAIM FOR RELIEF

COUNT I

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION AND 2 OF THE SHERMAN ACT

132. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

133. Section 2 of the Sherman Act, 15 U.S.C. § 2, provides in pertinent part that:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . . .

134. Defendants knowingly and willfully engaged in a course of conduct designed to obtain and extend their monopoly power in the relevant market. This conduct included the

procurement of the '579 patent that Defendants knew to be both invalid as obvious in view of the prior art and unenforceable for inequitable conduct before the PTO, improperly listing the '579 patent in the Orange Book, and improperly filing and prosecuting objectively baseless patent infringement actions against companies seeking to market competing versions of Protonix. Defendants' conduct was designed to delay the introduction of generic formulations of Protonix into the market.

135. Defendants intentionally and wrongfully maintained their monopoly power with respect to Protonix in violation of Section 2 of the Sherman Act. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their Protonix purchases.

136. Plaintiff and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of paying higher prices for their Protonix purchases than they would have paid in the absence of those violations. This is the sort of injury that antitrust laws were designed to prevent and flows from that which make Defendants' conduct unlawful. Plaintiff is the proper entity to bring a case concerning this conduct.

137. Plaintiff and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Section 2 of the Sherman Act.

138. Plaintiff and the Class further seek injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar

anti-competitive conduct does not occur in the future.

COUNT II

FOR COMPENSATORY AND MULTIPLE DAMAGES, PENALTIES, AND DECLARATORY AND INJUNCTIVE RELIEF, UNDER STATE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES

139. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

140. Defendants conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

a. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;

b. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;

c. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;

d. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §§ 501.201, *et seq.*;

e. Iowa: The aforementioned practices by Defendants were and are in

violation of the Iowa Competition Law, Iowa Code §§ 553.01 *et seq.*;

f. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50-623, *et seq.*;

g. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;

h. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*

i. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.,* and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;

j. Mississippi: The aforementioned practices by Defendants were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*, in that, *inter alia*, Mississippi consumers are forced to purchase Protonix from Mississippi pharmacies and vendors at supracompetitive prices;

k. Nebraska: The aforementioned practices by Defendants were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;

l. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.* in that, *inter alia*, Nevada consumers are forced to purchase Protonix from Nevada pharmacies and vendors at

supracompetitive prices;

m. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;

n. New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;

o. North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

p. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;

q. South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.,* and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;

r. Tennessee: The aforementioned practices of Defendants were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*, in that the conduct complained of had substantial effect on Tennessee commerce in that Tennessee consumers are forced to purchase Protonix from Tennessee pharmacies and vendors at supracompetitive prices;

s. Utah: The aforementioned practices of Defendants were and are in violation of the Utah Trade Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.*, the Utah Consumer

Sales Practices Act, Utah Code Ann. §§ 13-11-1, *et seq.*, and the Utah Antitrust Act, Utah Code Ann. § 76-10-919;

t. Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;

u. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*; and

v. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*, and has substantially affected the people of Wisconsin and has had substantial impacts within Wisconsin in that Wisconsin consumers are forced to purchase Protonix from Wisconsin pharmacies and vendors at supracompetitive prices.

141. As a result of the conduct described above, Plaintiff and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of Protonix, and paying prices for such products that were higher than they would have been but for Defendants' improper actions. The full amount of such damages is presently unknown and will be determined after discovery and upon proof at trial. Plaintiff and the Class seek damages, multiple damages, treble damages, and penalties as permitted by state law for their injuries caused by these violations pursuant to these statutes.

142. Plaintiff and the Class also hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through the scheme set forth herein is unlawful. Plaintiff and the Class further seek equitable and injunctive relief to correct for the anticompetitive market effects and other harms to purchasers caused by the unlawful conduct of

Defendants, and other relief so as to assure that similar conduct does not occur in the future.

COUNT III

FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR UNJUST ENRICHMENT BY DEFENDANTS

143. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

144. As a result of their unlawful conduct described above, Defendants has been and will continue to be unjustly enriched. Specifically, Defendants has been unjustly enriched, to the detriment of Plaintiff and the Class by the receipt of, at a minimum, unlawfully inflated prices and/or illegal monopoly profits on their sale of Protonix.

145. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of its ill-gotten gains resulting from the overpayments for Protonix made by Plaintiff and the Class.

146. Plaintiff and members of the Class are entitled to the amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiff and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiff and the Class members may make claims on a *pro rata* basis.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that:

(a) declare Plaintiff as the representative of the Class;

(b) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiff's claims for declaratory, injunctive, and equitable relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and

(c) the conduct alleged herein be declared, adjudged and decreed to be in violation of Sections 1 and 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;

(d) Defendants be enjoined from continuing the illegal activities alleged herein;

(e) Plaintiff and each member of the Class be awarded damages and, where applicable, treble, multiple, and other damages, according to the laws of the Indirect Purchaser States, including interest;

(f) Plaintiff and each member of the Class recover the amounts by which Defendants have been unjustly enriched;

(g) Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law;

(h) Plaintiff and the Class be granted such other and further as the Court deems just and necessary.

JURY DEMANDED

Plaintiffs demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Respectfully submitted,

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